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09/872,526	06/01/2001	Peter M. Bonutti	BON-1360-7	3309
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PAUL D. BIANCO Fleit Gibbons Gutman Bongini & Bianco PL 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

09/872,526

Applicant(s)

BONUTTI, PETER M.

Examiner

Anu Ramana

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36, 38-43, 46-50, 53, 57, 59-61 and 66-111 is/are pending in the application.
- 4a) Of the above claim(s) 68-79, 86 and 87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36, 43, 46-50, 53, 57, 59-61, 66, 67, 84-85, and 88-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/25/2009
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claim 94 is objected to because of the following informalities. It depends on claim 96. Appropriate correction is required.

Claim 94 is also objected to under 37 CFR 1.75 as being a substantial duplicate of claim 92. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's disclosure, as originally filed, does not provide support for how viability of the tissue is maintained. For examination, the Examiner is assuming any procedure that does not excessively manipulate tissue during extraction to meet this limitation.

Claims 101-108 and 110-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Regarding claims 101-108, Applicant's disclosure, as originally filed, does not provide support for: (1)

positioning a trocar with respect to the cannula; (2) positioning the cannula with a trocar; and (3) positioning a trocar within the cannula.

Regarding claims 110-111, Applicant's disclosure, as originally filed, does not provide support for use of additional instrumentation with the cannula of the removal apparatus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how viability of the tissue is maintained.

In claims 110 and 111, the recitation "step of passing at least a portion of an instrument into the cannula" renders the claims vague and indefinite since it is unclear what this instrument is. The cannula referred to in claims 36 and 84 is the cannula associated with the removal step not the introduction step (as illustrated in Fig. 19 of Applicant's disclosure).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36, 38-40, 46-50, 53, 57, 59-61, 66-67, 84-85, 88, 90-96, 99 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Rudall K.M., Wickham, G.

A., "Development of wool follicles and fibers on autoplasic grafts of stored foetal lamb skin," pp. 75-88 of book titled "Biology of the skin and hair growth," Americal Elsevier Publishing Company, Inc., 1965 (hereafter Rudall et al.) in view of Kellogg (US 3,606,878).

Rudall et al. disclose the method steps of: obtaining fetal tissue percutaneously from the donor or fetus; irrigating or immersing the tissue in glycerol; maintaining sterility of the excised tissue; treating the graft with a material such as serum or a biodegradable material or polymer or adhesive element or fibrin or "tissue grafts"; and implanting the graft material in a patient, i.e., the delivered lambs (pages 76-78).

Rudall et al. disclose all elements of the claimed invention except for using a cutting or removal device to excise tissue utilizing suction and irrigation to move tissue along a passage of the device wherein the cutting device includes a flexible shaft, a rigid outer member or cannula, a cutting tip mounted on a distal portion of the flexible shaft, a drive means connected to the flexible shaft, and aspiration openings located on an outer periphery of the cutting tip (pages 1066-1067).

Kellogg teaches a needle instrument for biopsy or tissue extraction including: a rigid outer member or cannula 10; a flexible shaft 22 connected to a cutting tip (24, 26), the cutting tip including aspiration openings 26a, 26b spaced from a distal end of the cutting tip (Figs. 4 and 5, col. 2, lines 40-65, col. 3 and col. 4, lines 1-37).

Regarding claim 38, the step of rotating motion to move the cutter within the cannula is inherent to cutting tissue drawn into the instrument by suction.

Regarding claim 39, Kellogg clearly teaches the use of reciprocating motion, namely, insertion followed by withdrawal, of the cutter within the cannula (col. 3, lines 40-75).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a cutting device, as taught by Kellogg, to cut tissue in the practice of the Rudall et al. method, since it was well known to use suction in conjunction with cutting to aid extraction of tissue.

The claimed method steps are rendered obvious by the above discussion.

Response to Arguments

Applicant's arguments filed 12/10/2009 have been fully considered.

New claims 86 and 87 have been withdrawn from consideration since they are directed to a non-elected invention. Rejoinder of withdrawn claims 68-79, 86 and 87 will be considered when an allowable generic claim is present in the instant application.

Applicant's arguments with respect to the rejections under 35 USC 103(a) over Rudall et al. in view of Kellogg are not persuasive. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

It is the Examiner's position that Rudall et al. clearly disclose percutaneously obtaining tissue from the fetus or donor. Rudall does not disclose the use of a cannula with a cutting device disposed therein to obtain fetal tissue. Kellogg teaches a device used for tissue extraction, including an outer cannula and a flexible shaft with a cutting tip disposed therein. Based on this teaching, one of ordinary skill in the art would have utilized the Kellogg device to percutaneously obtain tissue from the donor or fetus in the method of Rudall et al., to arrive at the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
March 29, 2010

/Anu Ramana/
Primary Examiner, Art Unit 3775

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